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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,730	12/24/2001	Kenji Sawa	10873.853US01	4134
7590 03/19/2004				
Merchant & Gould P.C. P.O. Box 2903 Minneapolis, MN 55402-0903		EXAMINER MENON, KRISHNAN S		
		ART UNIT PAPER NUMBER		
		1723		

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,730

Applicant(s)

SAWA, KENJI

Examiner

Krishnan S Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on RCE of 2/27/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-7 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sacco (US 5,059,173).

Claim 1: Sacco teaches a method of composing an infusion line comprising a spike unit (13,45) a main tube unit (12 at 27; line connecting 13, 43,40,30, etc.), an infusion filter unit (50), and a one-way valve unit (49), each unit being formed from one or more components (see figures), spike unit being at one end (see fig 1), and the distal end with respect to the spike unit having a connector for access to a patient (17).

Sacco does not specifically state the method as 'determining a composition' of an infusion line. However, it would be obvious to one of ordinary skill in the art at the time of invention that Sacco having made an infusion line for the process of infusion would have to first determine the composition needed in the infusion line before building the infusion line. Regarding the 'standardized shapes and sizes so that a single size connector is capable of connecting the plural kinds of units together', changes of size, shape, etc without special functional significance are not patentable. *Research Corp. v. Nasco Industries, Inc.*, 501 F2d 358; 182 USPQ 449 (CA 7), cert. denied 184 USPQ

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193; 43 USLW 3359 (1974). Sacco teaches standardizing (though the specific word 'standardize' is not used) in col 1 line 42- col 3 line 10.

There is an extension tube as in claim 2 and 3, distal to the spike unit (12 at 17). Spike unit is connecting the infusion line to a supply source (14), main tube unit adjusts the length between the spike unit and other units positioned in the patient side (see fig 1), injection device (53) is positioned between the main tube unit and the extension tube and could be used for injecting medicines, infusion filter is positioned between the main tube unit and the extension tube (see 40), one-way valve is positioned on the opposite side of the spike unit with respect to the main tube unit to prevent back flow of infusion fluid (49), all as in claim 4. Claim 5 further adds the limitation of the extension tube positioned on the patient side allowing the infusion line to be held at hand of the patient (see fig).

Re the newly added limitation of 'determined to be included' in the instant claims, it would be obvious to one of ordinary skill in the art at the time of invention that Sacco having made an infusion line for the process of infusion would have to first determine the composition needed in the infusion line before building the infusion line.

2. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urquhart et al (US 4,552,556)

Urquhart teaches a method of composing an infusion line comprising a spike unit (52-fig 2), a main tube unit (54) and an infusion filter unit (58; 142-fig 13; col 14 lines 13-31) as in claim 1. The method further comprises composing an extension tube to the

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end on the distal side with respect to the main tube unit as in claims 2 and 3 (23-fig 2).

Urquhart does not specifically state the method as 'determining a composition' of an infusion line or unit groups 'determined to be included'. However, it would be obvious to one of ordinary skill in the art at the time of invention that Urquhart having made an infusion line for the process of infusion would have to first determine the composition needed in the infusion line before building the infusion line. Regarding the 'standardized shapes and sizes so that a single size connector is capable of connecting the plural kinds of units together', changes of size, shape, etc without special functional significance are not patentable. *Research Corp. v. Nasco Industries, Inc.*, 501 F2d 358; 182 USPQ 449 (CA 7), cert. denied 184 USPQ 193; 43 USLW 3359 (1974).

3. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sacco (173) in view of Urquhart et al (US4,552,556).

Sacco teaches all the limitations of claims 1 and 2. Claims 6 and 7 add further limitations of spike unit including a spike and a drip chamber, which Sacco does not teach. [Sacco has the spike drip chamber down-stream of the filter, away from the spike unit]. Urquhart teaches a spike unit having a spike and a drip chamber (see 15-17, fig 1, and col 4 lines 65-68). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Urquhart in the teaching of Sacco to have the spike and the drip chamber together so that the drip chamber can be used to trap air in addition to adjust the flow rate, as taught by Urquhart. Additional limitations of claims 6 and 7 as taught by Sacco are: main tube having a clamp and connector (line 12 or 25 at 50), injection device including a connector and an injection port (52), infusion filter

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has a filter, tube and connector (40), one-way valve unit has a valve and a connector (49), extension tube has a tube and a connector (12 at 17). Re the newly added limitation of 'determining the composition', it would be obvious to one of ordinary skill in the art at the time of invention that Sacco in view of Urquhart having made an infusion line for the process of infusion would have to first determine the composition needed in the infusion line before building the infusion line.

Response to Arguments

Applicant's arguments filed 11/24/03 have been fully considered but they are not persuasive.

Re Applicant's argument that Sacco and Urquhart do not suggest standardization of shapes and sizes, standardization of shapes and size is not patentable as pointed out in the rejection. The same is true for classification and selection. Arrangement of the components leads to a structure for the product, which is anticipated by the reference. It may also please be noted that Sacco's discussion of the background of his invention and the objects and summary of the invention describe the need for standardization, even though the word 'standardization' is not used.

Conclusion

This is an RCE of applicant's earlier Application No. 10/035,730. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had

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been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan Menon
Patent Examiner


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